

## REMARKS

Claims 1-5 and 7-19 were pending in this application. Claims 1, 11 and 12 have been amended. Claims 4, 10 and 19 have been canceled. Claims 20-22 have been added. No new matter has been added. Claim 20 further clarifies the feature that the marker is an integral part of the implant and degrades over time.

## ARGUMENTS

Applicant respectfully traverses the Examiner's assertion that the references are appropriately combinable. Heublein and Stinson are not concerned with a similar technical difficulty. The only common point is that they are directed to medical implants. Heublein discusses biodegradability whereas Stinson is focused on the problem of radiopacity. Biodegradability and radiopacity are fundamentally different problems and require very different solutions. Biodegradability addresses the degradation of material safely into the surrounding environment over time. Radiopacity addresses making the implant detectable to detection devices to better locate the implant during insertion. While Heublein mentions using gold, the Examiner has not shown any indication where Heublein addresses radiopacity or where one of ordinary skill in the art would be expected to derive such disclosure that could be construed as addressing a similar technical difficulty as Stinson. Moreover, the opaque marker is not part of the implant structure, rather, it is tethered to or wrapped around the implant for retrieval after the implant is positioned. Neither reference addresses the need for a marker that is both biodegradable and radiopaque and which at the same time can be an integral part of the implant.

Designing a biodegradable radiopaque marker material that can be integrated with an implant without requiring redesign of the implant requires addressing several unique key issues, among which are: (a) choosing a biodegradable alloy component and a radiopaque marker component that will combine appropriately and exhibit both characteristics, (b) integrating the marker material with the implant (e.g., by coating or forming the marker as part of the implant structure), (c) making sure that the marker material does not flake off or crack or otherwise prematurely become dissociated from the implant and (d) having the marker degrade safely into

the environment over a period of time while the implant structure remains intact (or possibly degrades at its own rate). Prior attempts at achieving the foregoing have required redesigning the implant, which increases costs and research effort, or, as Stinson shows, requires a separate marker structure which is mechanically attached to the implant after the implant itself is formed. While Heublein discusses biodegradable alloys and Stinson discusses radiopaque alloys the two do not disclose, teach or suggest a combination of both alloys in a single marker material such that the above issues are addressed.

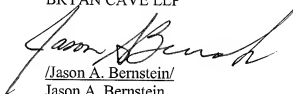
Stinson teaches away from the present invention. Stinson states: "A disadvantage of some permanent radiopaque markers is that they may compromise structural integrity, may not be biocompatible or biostable, and may be more thrombogenic than the implantable endoprosthesis" (col. 2, lines 24-27). Stinson teaches a temporary retrievable marker and a discrete permanent marker. Stinson is directed to a stent having, in one embodiment, a temporary removable marker that separates from the stent and is physically removed. The marker is not an integral part of the stent. The marker of Stinson is connected to the implant by a wire attached to a hook, knob, ring, etc. "Temporary radiopacity may be made by incorporating non-integral, retrievable radiopaque constituents into the implant" (col. 2, lines 43-45, emphasis added). Stinson teaches away from the marker as presently claimed which is integral with the implant and is essentially non-retrievable. Stinson also teaches: "An example of a discrete permanent marker is a coil, knot or ring of tantalum wire around a feature of a stent, such as a stent wire crossing point" col. 9, lines 9-10). In this instance the marker is still not an integral part of the implant, rather, it is mechanically attached and held in place by physical association, not by surface-to-surface bonding, such as by coating.

There is no reason to combine Heublein and Stinson. If Heublein discloses an opaque marker, as the Examiner states, there is no reason to use a completely separate radiopaque marker of Stinson. If Heublein does not disclose radiopacity, the combination of Heublein and Stinson do not result in the presently claimed invention as the two different problems of biodegradability and radiopacity are distinct and not similar and one skilled in the art would not have reason to combine the two without using hindsight.

### CONCLUSION

Applicant submits that the present application is in condition for allowance and respectfully requests such action. If the Examiner has any questions that can be answered by telephone, please contact the undersigned attorney of record at the telephone number listed below.

Respectfully submitted,  
BRYAN CAVE LLP



/Jason A. Bernstein/  
Jason A. Bernstein  
Reg. No. 31,236

One Atlantic Center, Fourteenth Floor  
1201 West Peachtree Street, NW  
Atlanta, GA 30309-3488  
(404) 572-6900  
(404) 572-6999 (fax)  
[jbernstein@pogolaw.com](mailto:jbernstein@pogolaw.com)